

## Claims

1. A polycationic carbohydrate or a pharmaceutically acceptable derivative thereof, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan, or a pharmaceutically acceptable salt or derivative thereof, a cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof, for use as an immunostimulant.

2. A polycationic carbohydrate according to claim 1 where the polycationic carbohydrate is a water-soluble alkylated chitosan derivative or a salt thereof, such as trimethyl chitosan chloride, N-carboxymethyl chitosan and polyethylene glycol chitosan.

3. A polycationic carbohydrate according to claim 2 in which the alkylated chitosan is a trimethylchitosan.

4. A pharmaceutical composition comprising a biologically active agent which is capable of generating a protective immune response in an animal, and a polycationic carbohydrate according to any one of claims 1 to 3.

5. A pharmaceutical composition according to claim 4 which further comprises a diluent or carrier.

6. A pharmaceutical composition according to claim 5 which comprises particles comprising

- (i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;
- (ii) a first material capable of forming particles; and
- (iii) a polycationic carbohydrate according to any one of claims 1 to 3.

7. A pharmaceutical composition comprising particles, each particle comprising

- (i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;
- (ii) a first material capable of forming particles; and
- (iii) one or more polycationic carbohydrates which have immunostimulant properties, wherein polycationic carbohydrate is distributed throughout the particle including at the surface.

8. A composition according to claim 7 wherein the polycationic carbohydrate comprises an immunostimulant which is a chitin derivative, a cationic polypeptide, a cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

9. A composition according to claim 8 wherein the polycationic carbohydrate comprises a chitin derivative.

10. A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2 or claim 3.

11. A composition according to any one of claims 6 to 10 wherein the particle comprises microspheres, microparticles or liposomes.

12. A composition according to claim 11 wherein the particle comprises a microparticle.

13. A composition according to any one of claims 6 to 12 wherein the first material is a polymeric material which has a molecular weight of 100kDa or more.

14. A composition according to any one of claims 6 to 13 wherein the first material comprises poly-(L-lactide).

15. A composition according to any one of ~~claims 6 to 14~~ wherein the ratio of the first material to the polycationic carbohydrate is from 99:1 to 9:1 w/w.

16. A composition according to any one of ~~claims 6 to 15~~ wherein the biologically active agent is capable of generating a protective immune response against tetanus, diphtheria, or *Yersinia pestis*.

17. A composition according to ~~claim 16~~ wherein the biologically active agent comprises a combination of the V antigen of *Y. pestis* or an immunologically active fragment thereof, and the F1 antigen of *Y. pestis* or an immunologically active fragment thereof.

18. A composition according to any one of ~~claims 6 to 17~~ which is adapted for intranasal application.

19. A composition according to any one of ~~claims 6 to 17~~ which is adapted for parenteral administration.

20. A composition according to any one of ~~claims 6 to 19~~ which further comprises a chemical compound selected from

- A) a polyamino acid,
- B) a vitamin or vitamin derivative,
- C) cationic pluronics,
- D) a clathrate,
- E) a complexing agent,
- F) cetrinides;
- G) an S-layer protein; or
- H) methyl-glucamine.

21. A composition according to ~~claim 20~~ which further comprises a cationic pluronic.

22. A composition according to ~~claim 21~~ which comprises nanospheres of a cationic pluronic which are surface modified with chitosan.

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AC 23. A method ~~for producing a pharmaceutical composition, which~~  
method comprises encapsulating a biologically active agent in a first  
material, in the presence of a polycationic carbohydrate according to  
any one of claims 1 to 3.

24. A method for producing a pharmaceutical composition, which  
method comprises forming an emulsion of a biologically active agent  
and a first polymeric material, in the presence of an immunostimulant  
polycationic carbohydrate, and dropping the resultant emulsion into a  
secondary aqueous phase which also contains an immunostimulant  
polycationic carbohydrate.

25. A method according to claim 24 wherein the immunostimulant  
polycationic carbohydrate is a chitin derivative, cationic  
polypeptide, cationic polyamino acid, a quaternary ammonium compound  
or a mixture thereof.

26. A method according to claim 25 wherein the polycationic  
carbohydrate is chitosan, chitosan chloride, chitosan glutamate or a  
water-soluble alkylated chitin derivative according to claim 2 or  
claim 3.

27. A method for producing a pharmaceutical composition which method  
comprises forming a microsphere, depositing a layer of polycationic  
carbohydrate thereon, and thereafter adsorbing a biologically active  
agent.

28. A method according to claim 27 wherein the immunostimulant  
polycationic carbohydrate is a chitin derivative, cationic  
polypeptide, cationic polyamino acid, a quaternary ammonium compound  
or a mixture thereof.

29. A method according to claim 28 wherein the polycationic  
carbohydrate is chitosan, chitosan chloride, chitosan glutamate or a  
water-soluble alkylated chitin derivative according to claim 2 or  
claim 3.

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a?

d of protecting an animal against a  
ministering to said animal, a prote  
late the animal's immune system to  
ective against said pathogen, in th  
ccording to any one of claims 6 to

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according to ~~claim 32~~ w  
mulant are applied to a  
according to ~~claim 33~~ w  
surface.

of a polycationic carbocationic derivative thereof according to the present invention, in the preparation of a stimulant, for therapeutic treatment of a patient.

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